

REMARKS

Amendments to the claims have been made to respond to the issues and concerns raised in the Office Action, to clarify aspects in the specification and claims, and to refine claim language. The amendments are believed to be consistent with the disclosure originally filed. The amendments also have been particularly presented to avoid, where applicable, any admission or estoppel, generally, negatively affecting the scope of protection provided by the disclosure and claims of the present application, and also in a manner that avoids prosecution history estoppel, limitation of the scope of equivalences, or the like. The Applicant amends claims 28-43 and 45-50. Claims 1-27 and 44 have been cancelled. Thus, claims 28-43 and 45-50 remain in this application and are believed in a condition for allowance.

As a preliminary matter, the Applicant notes that many of the issues and concerns related to the present case present complex and intertwining considerations. Accordingly, in the event questions remain, the Applicant requests the opportunity to pursue an interview to resolve any issues or concerns.

The Office Action raised a number of concerns under 35 U.S.C. § 112, First Paragraph, citing new matter issues. Although individual issues were not called out as such in the Office Action, the Applicant believes the following to address all of the new matter issues raised.

The Office Action questions if the specification teaches the broader concepts of utilizing, in any manner, estimates of certain economic costs, certain biological costs, certain economic gains, and certain biological gains. While the Applicant disagrees with any suggestion that the specification might not teach these concepts, please note that the Applicant has amended claim 28 to both replace the term "utilizing" with the term "estimating" and to remove any reference to the terms "biological cost" and "biological gain". As a result, claim 28 now refers only to estimating certain economic costs and estimating certain economic gains. These amendments are believed to fully respond to the issue raised in the Office Action and to be fully supported by the description, in as much as the Office Action expressly states that "[t]he specification teaches the use of estimates of economic cost and gain to evaluate the integrated herd management

system". The Applicant further notes that these amendments have been voluntarily implemented solely to aid the Examiner and to expedite examination of the application. The amendments should not be deemed as presenting any estoppel or the like and the Applicant expressly reserves the right to present the full scope of the prior claims at any time.

The Office Action also questions if the teachings in the specification of specific time intervals between inducing early puberty and harvesting were determined based on a time interval that results in a net economic gain and a net biological gain. The Applicant explains that they do. However, as to teaching a net biological gain, please note that the Applicant has amended claim 28 to remove all references to a biological gain. This amendment is believed to be fully responsive to the issue of biological gain raised in the Office Action. Please also note that these amendments have been voluntarily implemented solely to aid the Examiner and to expedite examination of the application. The amendments should not be deemed as presenting any estoppel or the like and the Applicant expressly reserves the right to present the full scope of the prior claims at any time.

As to teaching a net economic gain, it should be noted that this concept is explained in the description at page 1, lines 18-30. The description notes that in order for a SCH system to remain economically sustainable, the end product must be acceptable to the consumer. It further notes that carcasses of advanced maturity pose problems in palatability, and therefore may be penalized by financial discounts. The description further states that the USDA has set the approximate chronological age that corresponds to the physiological maturity score of "B" or greater to be 30 months or greater. However, as noted in the description, maturity scores may increase with increasing chronological age at a much faster rate than indicated by the USDA. Accordingly, the description suggests that animals 24 months of age and greater more accurately correspond to USDA maturity scores of "B" or greater. Therefore, as stated in the description, a target age of harvest for a SCH may be less than 24 months of age in order to minimize the risk of financial discounts and provide the consumer with a highly palatable product.

Reviewing these passages from the description, it is clear that a time interval is affirmatively set in order to promote the economic sustainability of the SCH system. Economic

sustainability is achieved by minimizing the financial discounts that result when the end product is not acceptable to the consumer. Lack of consumer acceptance, in turn, is a function of carcass maturity. While USDA guidelines suggest that harvesting prior to 30 months of age is acceptable to avoid a grade "B" maturity score, the description teaches harvesting at or prior to the earlier age of 24 months in order to more effectively avoid a grade "B" maturity score. The fact of harvesting to a stricter standard than USDA guidelines further indicates the affirmative nature of setting a time interval. In this manner, it is seen that the harvesting component of a time interval is affirmatively determined to result in a net economic gain.

Further, referring to the description at page 2, lines 1-4, it is stated that a production system in which a SCH is to rear a calf and be ready for harvest by 24 months of age may be accomplished by breeding the heifer at a non-traditional age of 9 months. By itself, the fact of breeding a heifer at a non-traditional age indicates the affirmative nature of determining a time interval. However, this point further is supported by noting that the 9-month breeding age is made necessary by having affirmatively selected a 24-month harvesting age. Also, as noted in the description, the carcass must be of high quality but must not sacrifice the quality of the progeny. These considerations are goals of the herd management system (with economic ramifications, as discussed above) that are promoted by breeding at the non-traditional age of 9 months, further indicating the affirmative nature of determining a time interval. In this manner, it is seen that the puberty induction component of a time interval is affirmatively determined to result in a net economic gain.

Other passages in the description further support the concept of affirmatively determining a time interval that results in a net economic gain. For example, at page 12, lines 6-7, the description states that early weaning may be accomplished to further shorten the time interval between birth and harvest of the animal while still allowing for one parturition for replacement. Inherent in the text reading "to further shorten" is the concept that a time interval may be variably selectable so as to allow for lengthening or shortening. Attention also is directed to page 12, lines 15-16, stating that the specific example and time line provided is not intended to limit the invention to that specific example of that time line. While this statement is made in the context of discussing the applicability of the invention to animals other than bovine, it

nevertheless remains illustrative of the point that the time interval may be affirmatively determined and varied in response to given factors in any specific application of the herd management system.

Additionally, the Applicant further anticipates augmenting the points discussed herein by supplying a supplemental affidavit from John Schenk, from whom an affidavit was submitted in response to the immediately prior Office Action. Although not available for submission at this time, the Applicant intends to supply the affidavit as soon as it becomes available. The Applicant anticipates that the affidavit will state that persons with skill in the art readily will recognize that the teaching of the present application related to a 9-month/24-month interval is merely one possible embodiment of an affirmatively determined interval for bovine applications, and further that the 9-month/24-month interval is merely one example of the broader concept taught by the present application of affirmatively determining a time interval to result in a net economic gain.

The Office Action makes numerous statements regarding the applicability of the invention to animals other than bovine. The Applicant disagrees with any suggestion that such applications might be new matter or otherwise not adequately described and notes that the description in several locations expressly states that the teachings of the description are applicable to non-bovine animals, including but not limited to page 26, lines 25-28, page 10, line 30, page 11, lines 13-14, and page 12, lines 13-16. As this is the case, the Applicant respectfully suggests that a new matter rejection is not warranted. However, please note that the Applicant has amended all claims to recite only "nonhuman traditionally herd-managed female mammals". The Applicant believes this recitation fully responds to the issues raised in the Office Action, and in particular accommodates the statement of the Office Action that "the claims broadly encompass the use of any nonhuman mammal and are not limited to animals that are conventionally managed in a system in which each animal used for breeding is slaughtered after the birth of their offspring". Additionally, further arguments in support of this recitation are presented elsewhere in these remarks. Please also note that these amendments have been voluntarily implemented solely to aid the Examiner and to expedite examination of the

application. The amendments should not be deemed as presenting any estoppel or the like and the Applicant expressly reserves the right to present the full scope of the prior claims at any time.

The Office Action makes numerous statements regarding the terms "biological cost", "biological gain", and "biological efficiency". While the Applicant disagrees with any concerns, please note that the Applicant has amended all claims to remove the terms "biological cost" and "biological gain". Please note that these amendments have been voluntarily implemented solely to aid the Examiner and to expedite examination of the application, and are believed to fully respond to the issues raised in the Office Action with respect to the terms "biological cost" and "biological gain". The amendments should not be deemed as presenting any estoppel or the like and the Applicant expressly reserves the right to present the full scope of the prior claims at any time. As to the term "biological efficiency", attention is directed to the description at page 2, lines 6-9, where the term is expressly stated and defined in terms of a greater proportion of total feed used for weight production and a smaller amount of feed used for maintenance, lactation, gestation, and body condition score as the cow herd becomes younger. Accordingly, the Applicant respectfully believes any new matter concerns as applied to the term biological efficiency" are not warranted.

The Office Action raised a number of aspects under 35 U.S.C. § 112, First Paragraph, citing enablement questions. Although individual issues were not called out as such in the Office Action, the Applicant believes the following to address all of the enablement questions raised.

As stated elsewhere in these remarks, the Office Action makes numerous statements regarding the applicability of the invention to animals other than bovine. Although the Applicant disagrees with these statements, please note that the Applicant has amended all claims to recite only "nonhuman traditionally herd-managed female mammals". The Applicant believes this recitation fully responds to the issues raised in the Office Action, and in particular accommodates the statement of the Office Action that "the claims broadly encompass the use of any nonhuman mammal and are not limited to animals that are conventionally managed in a system in which each animal used for breeding is slaughtered after the birth of their offspring". Please also note that these amendments have been voluntarily implemented solely to aid the

Examiner and to expedite examination of the application. The amendments should not be deemed as presenting any estoppel or the like and the Applicant expressly reserves the right to present the full scope of the prior claims at any time.

However, the Applicant additionally notes that as long as the specification discloses at least one method for making and using the claimed invention that bears a reasonable correlation to the entire scope of the claim, then the enablement requirement of 35 U.S.C. § 112 is satisfied. MPEP § 2164.01(b). How a teaching is set forth, by specific example or broad terminology, is not important. MPEP § 2164.08. Claims are not to be rejected as broader than the enabling disclosure under 35 U.S.C. § 112 for noninclusion of limitations dealing with factors which must be presumed to be within the level of ordinary skill in the art. *Id.* The claims need not recite such factors where one of ordinary skill in the art to whom the specification and claims are directed would consider them obvious. *Id.*

The Applicant notes that the specification discloses at least one method of making and using the claimed herd management system, as set forth in the embodiments applicable to bovines. Pursuant to the concepts discussed in the specification and as clarified in these and other remarks submitted to the Office, the Applicant maintains that numerous specific examples of the teachings of the invention have been made with regard to bovines. Referencing certain issues called out in the Office Action, these specific examples include but are not limited to those related to time intervals (pages 1-2, pages 11-12), typical numbers of sperm (page 10, lines 16-24), early weaning (page 3, lines 3-7, page 9, lines 12-15, page 11, lines 10-18, page 12, lines 1-11, page 14, lines 5-11), synchronizing estrous (page 12, lines 18-21, page 21, lines 21-29), slaughtering and replacing female animals (page 11, lines 21-29), and accomplishing a single parturition (page 12, lines 4-8).

The Applicant further notes that the broad concepts related to operating the herd management system are disclosed (See *e.g.* page 11, lines 19-30, and page 12, lines 1-16), and the specific examples related to bovines merely provide an example of operation of the herd management system in the context of one type of traditionally herd-managed animal. Because the teachings of the broad concepts of the herd management system are disclosed, and because

these broad concepts are supplemented by way of example to one type of traditionally herd-managed animal, the Applicant maintains that one of ordinary skill in the art would be able to review the teachings of the present case and apply them to other types of traditionally herd-managed animals without the necessity of undue experimentation. By way of illustration, the Applicant sets forth as follows how this may be accomplished for one aspect of the invention called out by the examiner, that of inducing early puberty, but it should be noted that all aspects of the invention may be made similarly applicable to other types of traditionally herd-managed animals. In this manner, it may be appreciated that the Applicant has set forth at least one method for making and using the claimed invention that bears a reasonable correlation to the entire scope of the Applicant's claims.

With respect to inducing early puberty, the specification discloses at least one method of inducing early puberty in bovine mammals. This teaching is made by way of the specific examples found at pages 2, 11, 17-18, and 34-35 of the description. Importantly, this disclosure is reasonably correlated to the entire scope of the claims. This is because the factors as applied to non-bovine mammals are of such a kind that are within the level of ordinary skill in the art. Specifically, the specification discloses that "diet is an effective tool to induce puberty." Specific examples of controlling diet in this manner are described in detail for one embodiment of the invention, bovine mammal herd management. The examples include use of a high energy diet; use of a diet high in propionate production in the rumen; use of a diet containing ionophores; inducing a weight gain of about 1.3 kg to 1.4 kg per day; use of a feedlot ration containing triticale grain, sunflower meal pellet, corn ground alfalfa, protein supplement and Rumensin⁷; adjusting the feedlot ration according to weight gain; and achieving by 9 months of age a target weight of 65% of mature weight.

As must be recognized, the test of enablement is whether one reasonably skilled in the art could make or use the invention from the disclosures in the patent coupled with information known in the art without undue experimentation. MPEP § 2164.01. Even a fact that experimentation may be complex (which is not typically the case here) does not necessarily make it undue, if the art typically engages in such experimentation. *Id.* An extended period of experimentation may not even be undue if the skilled artisan is given sufficient direction or

guidance. MPEP § 2164.06. Even a considerable amount of experimentation is permissible, if it is merely routine, or if the specification in question provides a reasonable amount of guidance with respect to the direction in which the experimentation should proceed. *Id.*

Here, because the specific techniques of using diet to induce early puberty are set forth for bovine mammals, the task of altering these techniques to apply to non-bovine mammals can be accomplished by routine experimentation or experimentation that is not undue. In as much as the specification lists the specific factors that can contribute to induce early puberty – including use of a high energy diet; use of a diet high in propionate production in the rumen; use of a diet containing ionophores; inducing a weight gain of about 1.3 kg to 1.4 kg per day; use of a feedlot ration containing triticale grain, sunflower meal pellet, corn ground alfalfa, protein supplement and Rumensin 7; adjusting the feedlot ration according to weight gain; and achieving by 9 months of age a target weight of 65% of mature weight – the specification provides a reasonable amount of guidance with respect to the direction in which the experimentation should proceed for the skilled artisan. Consequently, the applicability of the method to non-bovine mammals is well within the ordinary skill in the art, and the specification need not recite these factors to be enabling.

Additionally, the Applicant further anticipates augmenting the points discussed herein by supplying a supplemental affidavit from John Schenk, from whom an affidavit was submitted in response to the immediately prior Office Action. Although not available for submission at this time, the Applicant intends to supply the affidavit as soon as it becomes available. The Applicant anticipates that the affidavit will further support the point that a person of ordinary skill in the art, upon review of the Applicant's disclosure and with the knowledge available in the art, would be able to apply the teachings of the present case to traditionally herd-managed animals other than bovines without undue experimentation.

The Office Action questions if only by using a simulation in which pregnancy rates and calf survival rates were increased did the IS achieve profitability over traditional management systems, and that based on the teachings of the specification it is unclear if pregnancy rates and calf survival rates could be increased to the levels of the simulation under the conditions set forth

in the claims. They could, and the Applicant respectfully disagrees with any suggestion to the contrary. In fact, the specification expressly explains the reasons behind the pregnancy rates and the calf survival rates and points out that these reasons were due to factors unrelated to operation of the herd management system. Rather, these reasons were due to factors that may be readily identified and corrected for. Accordingly, these factors fall within the realm of predictable conditions and can be adjusted for by simulation to achieve the desired results.

With regard to pregnancy rates, as indicated in the description at the table on page 40 and on page 40, line 20, only 20 animals were used in the description. Further, the description at page 41, lines 4-6, expressly states that the result of the data set of 69% calves of desired sex conceived to sexed semen is not an adequate replication of the study by Seidel, as too few individuals were used. Importantly, as stated in the description at page 40, lines 3-4, Seidel reported that 86% of calves conceived from sexed semen were of the desired sex. The description further states at page 40, lines 6-7, that the low percent of desired sex was not expected as the true percent as X-chromosome sperm varied from 86%-92% for the batches of semen used in the description.

Given the low number of individual animals used in the description, and given that Seidel achieved 86% pregnancy rates for offspring of the desired sex by using a greater number of individual animals, the Applicant maintains that the pregnancy rates achieved in the description were merely the result of using too few individual animals to be statistically adequate, among other factors. Importantly, the pregnancy rates achieved in the description were not a result of factors related to the herd management system. Rather, they were the result of a problem that may be predictably identified – the use of too few individual animals, or the like – and that may be predictably remedied – *i.e.*, by using a statistically adequate number of animals, *etc.*

Further, in as much as the Seidel study did use a statistically adequate number of individual animals and achieved pregnancy rates of 86% for offspring of the desired sex, the Applicant maintains that an 80% pregnancy rate for offspring of the desired sex is in fact an accurate reflection of the pregnancy rates that would be achieved under one embodiment of the herd management system in actual practice. The use of the 80% pregnancy rate in assessing the

herd management system therefore in fact is an appropriate figure to assess the herd management system, as is stated in the description at page 51, lines 4-5.

The Applicant also notes that the low number of individual animals used in the study was identified elsewhere in the application as a factor in interpreting the results. For example, on page 40, lines 14-16, the description notes that the small number of samples (20 calves) poses a problem for statistical analysis and a conclusion that CE has no effect on calf morbidity, ADG, or weaning weights. This further supports the point that interpretation of pregnancy rates should be tempered by considering the effect of the low number of individual animals used in the description.

With regard to calf survival rates, the description expressly indicates that calf morbidity and mortality were due to factors unrelated to operation of the herd management system. Specifically, at page 41, lines 11-12, the description states that two of the seven deaths occurred as a result of dystocia, two more deaths were due to accidents, and the three remaining deaths were due to diphtheria. Further referencing the dystocia problems, the description at page 40, lines 5-12, further specifically states that the dystocia problems probably stem from sire selection rather than due to heifer size or age. Additionally, at page 41, lines 12-19, the description explains that morbidity may have resulted from inadequate calving facilities, including unsatisfactory manure management resulting in suboptimal udder cleanliness, labor difficulties caused by calving out of synchrony with herd-mates, limited space due to other feedlot animals occupying pens, and contributory time management problems among employees. Importantly, the calf survival rates achieved were not a result of factors related to the operation of the herd management system itself. Rather, they were the result of problems that may be predictably identified – dystocia, accidents, and disease – and that may be predictably remedied – by improving sire selection, implementing a safer environment for the animals, and improving the cleanliness and management of the feedlot.

The Applicant further anticipates augmenting the points above regarding pregnancy rates and calf survival rates by supplying a supplemental affidavit from John Schenk, from whom an affidavit was submitted in response to the immediately prior Office Action. Although not

available for submission at this time, the Applicant intends to supply the affidavit as soon as it becomes available. The Applicant anticipates that the affidavit will describe the significant degree of difficulty associated with obtaining a full herd of animals upon which to demonstrate the operation of herd management techniques. Such difficulties include, but are not limited to, locating an available herd of animals, locating facilities to house and manage the animals, employing qualified individuals to manage the herd of animals, and paying costs and fees associated with managing the herd of animals. It is anticipated that the affidavit further will state that the difficulties in obtaining a herd of animals, combined with the limited resources often available to those engaged in academic and scientific pursuits, frequently results in a situation where persons wishing to study herd management practices must do so pragmatically based on animals, facilities, and conditions as may be readily available. This may be done recognizing that even though higher quality animals, facilities, and conditions may be desirable -- and may be more representative -- they simply may not be practically obtainable. Consequently, studies of herd management practices often must be carried out under less than optimal conditions. Further, in evaluating the performance of such studies, it is typical to correct for such sub-optimal conditions in order to create an assessment of the herd management practices that fairly approximates typical operating conditions.

As concerns the herd management system of the present case, it is anticipated that the affidavit will state the pregnancy rates and calf survival rates were a result of sub-optimal numbers of individual animals available for study and sub-optimal feedlot conditions for the animals. The Applicant anticipates the affidavit further will state that these kinds of sub-optimal conditions are capable of predictable identification and predictable remediation. It further is anticipated that the affidavit will state the values used in the simulation were made merely to correct for the sub-optimal conditions experienced in the field in order to fairly approximate typical operating conditions.

The Office Action states that it may be unpredictable to sort sperm from any nonhuman mammal on the basis of a sex determination characteristic such that the resulting sample can be used to reproducibly generate 90% or more female offspring. The Applicant respectfully disagrees. The test of enablement is whether one reasonably skilled in the art could make or use

the invention from the disclosures in the patent coupled with information known in the art without undue experimentation. MPEP § 2164.01. Claims are not rejected as broader than the enabling disclosure under 35 U.S.C. § 112 for noninclusion of limitations dealing with factors which must be presumed to be within the level of ordinary skill in the art. MPEP § 2164.08. The fact that experimentation may be complex does not necessarily make it undue, if the art typically engages in such experimentation. MPEP § 2164.01. A single embodiment may provide broad enablement in cases involving predictable factors, such as mechanical or electrical elements. MPEP § 2164.03. If one skilled in the art can readily anticipate the effect of a change within the subject matter to which the claimed invention pertains, then there is predictability in the art. *Id.*

In the present case, as described in the specification on pages 7-8, the ability to sort sperm is provided through the use of flow cytometry. The use of flow cytometers to sort various types of cells, including sperm cells, is well known in the art. Indeed, many of the references supplied by the Applicant via Information Disclosure Statement and incorporated by reference in the present case expressly discuss various methods and apparatus related to the use of flow cytometers. As readily may be appreciated, a flow cytometer is a mechanical device having parameters which may be adjusted to direct its performance. It is well known that the accuracy of the sorting percentages achieved by a flow cytometer can be predictably varied by adjusting the parameters of the flow cytometer. As just one example, reducing the sort rate of a flow cytometer predictably increases the accuracy of the sorting percentages achieved by the flow cytometer. In this way, persons skilled in the use of flow cytometers readily may anticipate the effects that changing the parameters of the flow cytometer may have on sorting accuracy. While a degree of experimentation may be required in any given situation to adjust the parameters of the flow cytometer to achieve a desired accuracy of sorting percentages, such experimentation is not atypical in the field of flow cytometry and in any case is facilitated by the predictability of making adjustments to the flow cytometer. For these reasons, the Applicant maintains that the experimentation required to adjust a flow cytometer to achieve a desired accuracy of sorting percentages is not undue. Further, the Applicant maintains that the claims related to sorting sperm to accuracies sufficient to reproducibly generate 90% or greater offspring of the desired sex are not broader than the enabling disclosure of the description, because the factors required

to operate a flow cytometer to these requirements are within the level of ordinary skill in the art. Accordingly, the Applicant respectfully submits that the present claims are enabled, in as much as persons reasonably skilled in the art would understand the teachings of the present case related to operation of the herd management system, and would be able to sort sperm to the requisite accuracy of sorting percentages by operating a flow cytometer within the level of ordinary skill in the art.

The Applicant further anticipates augmenting the points discussed herein by supplying a supplemental affidavit from John Schenk, from whom an affidavit was submitted in response to the immediately prior Office Action. Although not available for submission at this time, the Applicant intends to supply the affidavit as soon as it becomes available.

The Office Action cites the results of the description at pages 40-41 to question if sorting sperm to generate 90% or more female offspring might be unpredictable. We respectfully disagree. As discussed elsewhere in these comments, the entire reasoning of which is applicable here, the results stated in the description were due to the low number of individual animals used in the description. Given that Seidel achieved 86% pregnancy rates for offspring of the desired sex by using a greater number of individual animals, the Applicant maintains that the pregnancy rates achieved in the description were merely the result of using too few individual animals to be statistically adequate, or the like.

The Office Action cites Fugger (1999; cited in the IDS of 6/12/01) to support the unpredictability of sorting sperm to high levels of purity. However, Fugger was concerned entirely with sorting human sperm, whereas the present case is entirely concerned with sorting non-human sperm. This is a significant distinction. As cited in the Office Action, Fugger expressly states that human sperm cells present unique characteristics that affect the ability to detect and separate X and Y sperm by flow cytometry. These unique characteristics include heterogeneity, substantial variance among individuals, oval shape, variance in the magnitude of difference in DNA content between X and Y chromosomes, and a relatively small 2.8% difference in total DNA content compared to greater than 3.5% for most domestic animals. In as much as these characteristics make sorting sperm to high levels of purity more difficult, it may

be expected that purity levels in sorted sperm for humans may be adversely affected. However, to the extent these considerations are unique to humans, as stated by Fugger and cited in the Office Action, these considerations are not attendant to sorting non-human sperm and therefore are not relevant to the present case.

The Office Action states that there are no teachings in the prior art as to how to overcome the problems associated with lack of difference in the DNA content between X and Y chromosome bearing sperm or the challenges posed by the shape, morphology, and heterogeneity of the sperm. Similarly, the Office Action cites Johnson (1992; page 13, cited in the IDS of 6/12/01) to illustrate the difference in DNA content among turkey sperm, human sperm, and rabbit sperm. To the extent that these animals are not traditionally herd-managed mammals, the Applicant maintains that the Johnson reference is inapposite to the present claims. Moreover, the Applicant further anticipates augmenting the points discussed herein by supplying a supplemental affidavit from John Schenk, from whom an affidavit was submitted in response to the immediately prior Office Action. Although not available for submission at this time, the Applicant intends to supply the affidavit as soon as it becomes available. The Applicant anticipates that the affidavit will support the point that overcoming the challenges posed by shape, morphology, and heterogeneity was well with the ordinary level of skill in the art at the time of the invention.

The Office Action raised certain concerns under 35 U.S.C. § 112, Second Paragraph, citing definiteness issues with respect to the terms "biological efficiency", "biological cost", and "biological gain". As described elsewhere in these remarks, the Applicant disagrees with the concerns raised in the Office Action. However, the Applicant has amended the claims to delete all reference to the terms "biological cost" and "biological gain". These amendments are believed to be fully responsive to the definiteness issues raised in the Office Action with respect to these terms. Please also note that these amendments have been voluntarily implemented solely to aid the Examiner and to expedite examination of the application. The amendments should not be deemed as presenting any estoppel or the like and the Applicant expressly reserves the right to present the full scope of the prior claims at any time. With respect to the term "biological efficiency", attention is directed to the description at page 2, lines 6-9, where the

term is expressly stated and defined in terms of a greater proportion of total feed used for weight production and a smaller amount of feed used for maintenance, lactation, gestation, and body condition score as the cow herd becomes younger. Accordingly, the Applicant respectfully requests withdrawal of the new matter rejection as it applies to the term "biological efficiency".

The Office action raised certain concerns under 35 U.S.C. § 112, Second Paragraph, citing definiteness issues with respect to the term "utilizing". As discussed elsewhere in these remarks, while the Applicant disagrees with the concerns raised in the Office Action, the Applicant has amended all claims to remove the term "utilizing", except as the term is used in claim 28, step d. With respect to claim 28, step d, it is believed use of the term "utilizing" in connection with the time interval described is definite in light of the discussion of the time interval stated elsewhere in these remarks. With respect to the amendments, these amendments are believed to be fully responsive to the definiteness issues raised in the Office Action with respect to the term "utilizing". Please also note that these amendments have been voluntarily implemented solely to aid the Examiner and to expedite examination of the application. The amendments should not be deemed as presenting any estoppel or the like and the Applicant expressly reserves the right to present the full scope of the prior claims at any time.

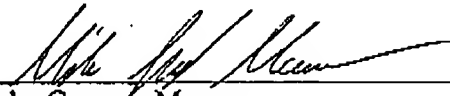
Finally, as stated elsewhere in these remarks, the Applicant again notes that the issues and concerns related to the present case present complex and intertwining considerations, and the Applicant considers that an interview to further effectively attempt to resolve these issues and concerns may be desirable. Accordingly, it is requested that the Examiner contact the undersigned to set a date for a personal interview to advance the case.

Dated this 15 day of December, 2004.

Respectfully submitted,

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